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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,988	12/28/2001	Ronald J. Pettis	500752999021	4336

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JONES DAY  
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NEW YORK, NY 10017

EXAMINER

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/028,988

Applicant(s)

PETTIS ET AL.

Examiner

Manuel Mendez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/31/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-34, 36-52 and 67-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-34, 36-52 and 67-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed 10/31/2005 have been fully considered but they are not persuasive. It is noted for the record that where there is reason to believe that a functional limitation asserted to be critical to establishing novelty in the claim subject matter may, in fact, be an inherent characteristic of the prior art, Applicant may be required to prove that the subject matter shown in the prior art does not possess the characteristic relied upon. In re Spada, 801 F.2d 1324, 660, 664, 169 USPQ 563, 566 (CCPA 1971). Applicant argues, "assuming *arguendo* Gross were used to inject a drug into the intradermal space, the claimed PK profile would not inevitably result". However, the fact that that a profile "**would not inevitably result**" cannot be interpreted to disclose that Gross definitely cannot provide the PK profile in question. The cited case law clearly imposes a requirement upon the applicant to provide evidence that Gross "does not provide the characteristic relied upon". The fact that there is a possibility that Gross can provide the claimed PK profile moots applicant's arguments concerning the merits of the Gross reference, and therefore, the pending rejections are maintained.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 31 and 32** are rejected under 35 U.S.C. 102(b) as being anticipated by **Gross, et al., (U.S. Patent No. 5,848,991)**. The cited patent discloses a method of delivering insulin and hormones intradermally (3:40-41; 6:56 - 7:20) using a single needle with an outlet at a depth of 250 micro m – 2 mm in a controlled manner based on needle diameter (4: 10-35). The plasma profile would be inherently similar to, but higher as compared to subcutaneous injection. Because Applicant argues that the needle length and enough pressure to control delivery are the essential limitations required to achieve the claimed method the limitations found in Gross would inherently allow the method disclosed in Gross to achieve a higher Cmax and AUC as compared to subcutaneous injection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 33-52 and 67-73** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gross in view of PURI (An investigation of the intradermal route as an effective means of immunization for microparticulate vaccine delivery systems) or D'Antonio, et al., (US Patent No. 6,056,716) and in further view of Ganderton, et al., (U.S. Patent No. 3,814,097), and Autret, et al., (Therapie 1991; 46:5-8)**. If the claimed method of intradermal delivery disclosed by Gross is not inherent, it would have been obvious to one of ordinary skill in the art to deliver drugs at particular pressures and flow rates to achieve higher Cmax and AUC than subcutaneous injection. Puri and D'Antonio disclose that intradermal injections give much greater Cmax values than subcutaneous. The prior art disclosures suggest a greater Cmax and AUC. (see Puri, pgs. 2609-2610, and D'Antonio col. 29, lines 3-9). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Puri or D'Antonio in the method of Gross in order to more effectively treat patients and save drug costs.

Concerning the use of multiple needle apparatuses, Ganderton, et al., (U.S. Patent No. 3,814,097) discloses injecting a substance through multiple needles. Moreover, concerning the infusion of hormones into the body, Autret, et al., (Therapie

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1991; 46:5-8) discloses the intradermal injection of a hormone that results in a pharmacokinetic profile similar to subcutaneous delivery. Based on the above observations, for a person of ordinary skill in the art, modifying the methods disclosed by Gross, PURI, and/or D'Antonio, et al., with the use of apparatuses having multiple needles and with the infusion of hormones would have been considered obvious in view of the conventionality of these enhancements.

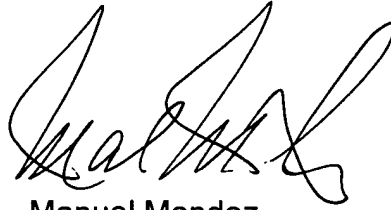
In view of the rejection to claims 67-73, this action is not a final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas Lucchesi can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Manuel Mendez', with a stylized, cursive script.

Manuel Mendez  
Primary Examiner  
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